DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

g1607d

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Alex Kim, President
Sushi House, Inc.
37-20 22nd Street
Long Island City, NY 11101

August 6, 2001

Ref: NYK-2001-108

Dear Mr. Kim:

We inspected your seafood processing facility, located at the above address, on July 20, 23, and 30, 2001 and found that you have serious deviations from the Seafood HACCP regulations (Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123)). These deviations, cause your raw tuna (a scombrotoxin (histamine) forming species of fish) roll/sushi products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through the links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, the firm's HACCP plan for your raw tuna roll/sushi products does not list the food safety hazard of histamine formation. Your plan should also list the critical control points (e.g., processing, refrigerated storage, etc.) for controlling histamine; the appropriate critical limits; the monitoring procedures to ensure compliance with the critical limits; the corrective actions to be taken in response to deviations from the critical limits; the record keeping system that documents the monitoring of critical control points; and the verification procedures to ensure the plan is being effectively implemented.

2. You must maintain adequate sanitation control records, to comply with 21 CFR 123.11(c). However, your firm's sanitation control records did not document monitoring for protection from adulterants and proper labeling, storage, and use of toxic compounds.

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

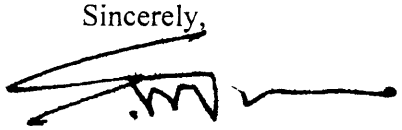
Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan and revised sanitation control

records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Form FDA 483) (copy enclosed) issued to and discussed with Ms. Susan Choe, Vice President at the conclusion of the inspection may not list all the deviations at your seafood processing facility. You are responsible for ensuring that your facility operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,



Edward W. Thomas
Acting District Director

Enclosure: Form FDA 483 dated July 23, 2001

Cc: HFR-NE1
Cc: HFR-NE100
Cc: HFR-NE140/QA file
Cc: HFR-NE150
Cc: HFR-NE1500/O. Vitillo
Cc: HFS-607/CFSAN
Cc: HFA-224
Cc: HFI-35
Cc: HFC-210/DCMO (FEI 3003387488)
Cc: EF (Sushi House, Inc., FEI 3003387488)
Cc: warning letter file (NYK-2001-108)
Cc: BAG

DCB approval 8/6/2001 LCA
FACTS 9419-0